



UNITED STATES PATENT AND TRADEMARK OFFICE

mi

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/938,669 | 08/27/2001 | Jens Petersen | 60117.000004 | 2508 |

7590 02/24/2004

Stanislaus Aksman
Hunton & Williams
Suite 1200
1900 K Street, N.W.
Washington, DC 20006

EXAMINER

AZPURU, CARLOS A

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1615

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 09/938,669 | Applicant(s) PETERSEN, JENS | |
| | Examiner Carlos A. Azpuru | Art Unit 1615 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 1-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>11/10/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of the amendment and response filed 11/10/03. The rejections under 35 USC 112, second paragraph; and 35 USC 103 are hereby withdrawn.

The following rejection is maintained in this action:

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 27-31 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18 and 19 of copending Application No. 09/938,667 ('667). Although the conflicting claims are not identical, they are not patentably distinct from each other because '667 claims a

Art Unit: 1615

prosthetic device which is injectable, and comprises a hydrogel which is made by reacting acrylamide, and methylene bis-acrylamide using a radical initiator. The result is a polyacrylamide gel. The amount of polyacrylamide gel can be less than 3.5% by weight, and should also contain at least 75% pyrogen-free water or saline solution. The prosthetic may also contain stem cells. The claims of '667 differ only in that the intended use of the prosthetic in that case is for prevention of incontinence and vesicoureteral reflux.. This is an intended use however, and does not lend a patentable distinction. Further, the instant claims are generic to soft tissue augmentation. It would have therefore been well within the skill of the ordinary practitioner to claim the instant claims given the claims of '667, with the expectation of providing reasonable soft tissue augmentation as provided in the urethra, colon or rectum in claims of '667. There are no unusual and/or unexpected results which would rebut prima facie obviousness. As such, the instant claims would have been obvious given the claims of '667.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 27-31 are 09/938,670 ('670) provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-15 of copending Application No. '670. Although the conflicting claims are not identical, they are not patentably distinct from each other because '670 claims an endoprosthesis which is injectable, and comprises a hydrogel which is made by reacting acrylamide, and methylene bis-acrylamide using a radical initiator. The result is a polyacrylamide gel. The amount of polyacrylamide gel can be less than 3.5% by

Art Unit: 1615

weight, and should also contain at least 95% pyrogen-free water or saline solution The prosthetic may also contain stem cells. It would have therefore been well within the skill of the ordinary practitioner to claim the instant claims given the claims of '670, with the expectation of providing reasonable soft tissue augmentation as provided in the claims of '670. There are no unusual and/or unexpected results which would rebut prima facie obviousness. As such, the instant claims would have been obvious give the claims of '670.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 27-31 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 27-35 of copending Application No. 09/938,668 ('668). Although the conflicting claims are not identical, they are not patentably distinct from each other because '668 claims a prosthetic device which is injectable, and comprises a hydrogel which is made by reacting acrylamide, and methylene bis-acrylamide using a radical initiator. The result is a polyacrylamide gel. The amount of polyacrylamide gel can be less than 3.5% by weight, and should also contain at least 75% pyrogen-free water or saline solution The prosthetic may also contain stem cells. The claims of '668 differ only in that the intended

Art Unit: 1615

use of the prosthetic in that case is for augmenting or replacing cartilage in the intra-articular cavity.. This is an intended use however, and does not lend a patentable distinction. Further, the instant claims are generic to soft tissue augmentation. It would have therefore been well within the skill of the ordinary practitioner to claim the instant claims given the claims of '667, with the expectation of providing reasonable soft tissue augmentation as provided for the cartilaginous tissues of '668. There are no unusual and/or unexpected results which would rebut prima facie obviousness. As such, the instant claims would have been obvious give the claims of '668.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

This application contains claims 1-26 drawn to an invention nonelected with traverse in Paper No. 03/03/2003. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

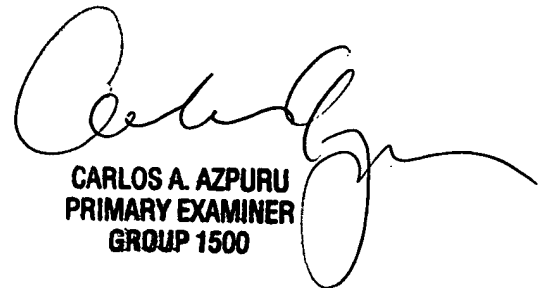
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0602. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0588. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ca



CARLOS A. AZPURU
PRIMARY EXAMINER
GROUP 1500